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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,344	12/22/2000	Peter Zhu	ASP-0010	1705

7590

09/23/2002

Philip S. Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

BARRY, CHESTER T

ART UNIT

PAPER NUMBER

1724

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,344

Applicant(s)

ZHU ET AL.

Examiner

Chester T. Barry

Art Unit

1724

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/22/00 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 - 21, drawn to a method, classified in class 210, subclass 767.
- II. Claims 22 - 31, drawn to a device, classified in class 210, subclass 198.1.

The inventions are distinct, each from the other because:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus, and the apparatus as claimed can be used to practice another and materially different process.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, because these inventions are distinct for the reasons given above and the search required for Group I and II is not required for Group II and I, respectively, restriction for examination purposes as indicated is proper.

During a telephone conversation with Theo. Shatynski on 9/18/02 a provisional election was made without traverse to prosecute the invention of Group II, claims 22-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 – 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The specification is objected to for want of specification of the application serial no. of docket ASP-009. Correction to "09/747230" is suggested.

The Sigma Chemical catalog product information for poly(L-lysine) hydrobromide is cited of interest. The info sheet is dated 12/18/96 (see page 3). The sheet, downloaded from the internet on 9/18/02, describes the material, including the P1524 material (MW >300 000), as a "white powder" material. That is, it is a solid. The product info sheet describes the HBr form as a "crystalline solid." The info sheet describes coating a solution of the polymer onto culture substrates, "glassware," and slides to facilitate adsorption / binding of cells to the substrate. The product info sheet does not explicitly describe provision of the solid polylysine in a "container" per se, but the skilled artisan would have understood that

Sigma, a chemical supply house, would provide and distribute this product in a container of some kind, such as an amber colored bottle, for example. Alternatively, "container," as recited in the claims, may reasonably be construed to read on the glassware, culture substrate, or slides described in the reference. None of containers so envisaged or shown in Sigma necessarily have a separate inlet and a separate outlet. A glass culture vessel, for example, may very well have but one opening for both inletting and outletting culture media therethrough. For example, an Erlenmeyer flask is one such culture vessel.

As is well known, polylysine is polymeric amino acid having not only the terminal amino group of all amino acids, but also one side chain amino group per lysine unit, as shown for example by Pine et al., Organic Chemistry, 4th ed., McGraw-Hill, p.787. Accordingly, solid primary amine reads on polylysine.

Similarly, the disclosure of Kem Medical's aldehyde spill clean-up kit employing **solid** CHEMSORB material based on the "same chemistry" as the glycine solution product, even if it were demonstrated on this record that it is the primary amino group at the heart of that chemistry, fails to describe a solid primary amino material ***in a container having an inlet***

and an outlet. CHEMSORB spill control pillows are not containers having inlets and outlets. Accordingly, claims 22 – 31 are allowable over the foregoing references.

However, USP 5998184 to Shi describes a bioreactor wherein cells are immobilized on a solid support by “peptide coated beads” (col 2 line 17) or polylysine encapsulated cells (col 6). As noted above, polylysine is a solid having pendant primary amino groups. Accordingly, **claim 22 is rejected under 35 U.S.C. Sec. 102(b) as anticipated by Shi.**

Claims 22 – 26, 31 are rejected under 35 U.S.C. Sec. 103(a) as obvious over Shi in view of Portier. USP 5534143 to Portier describes an immobilized cell packed bed bioreactor having a liquid waste inlet 21, 33 and treated liquid waste outlet 35. The patent suggests that such a reactor be used to decontaminate a wide variety of hazardous liquid wastes. It would have been obvious to have used the polylysine encapsulated cells of Shi in the hazardous waste decontamination bioreactor of Portier in view of Shi's suggestion to immobilize or entrap cells using polylysine. Alternatively, it would have been obvious to have fed hazardous liquid waste to the Shi bioreactor in view of Portier's suggestion to use immobilized cell bioreactors for

hazardous waste cleanup. In any event, the combined teachings of these references results in a device comprising a container with an in let and outlet and a source of solid primary amine within the container. The intended use of the device in an aldehyde removal method, does not limit the structure of the device itself.

USP 5352368 to Honeycutt describes and suggests decontamination of hazardous aldehyde liquid waste.

Claims 22 – 31 are rejected under the judicial doctrine of obviousness type double patenting over Claim 15 or USP 6399850 to Chen.

As the table below shows, pending claim 22 does not encompass

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Pending Application (limitations in this claim not found in the patented claim at right are underlined) (implied limitations are bracketed)	Patent 6399850 assigned to Ethicon (limitations in this claim not found in the pending claim at left are underlined)
22. A device for [neutralizing and] ¹ removing aldehydes from a waste stream comprising: a) a container <u>with an inlet and an outlet</u> ; and b) a source of <u>solid</u> primary amine <u>enclosed within the container</u> , wherein the solid primary amine neutralizes and removes the aldehyde from the waste stream.	15. A system for neutralizing aldehydes comprising: a container, <u>an aldehyde source comprising an aldehyde selected from the group consisting of ortho-phthalaldehyde, formaldehyde, and glutaraldehyde and configured to direct the aldehyde into the container</u> ; and an amino acid source comprising an amino acid <u>and configured to direct an amino acid into the container to yield a nonhazardous waste which has a LC₅₀ >500 mg/l</u> .

claim 15 by virtue of the requirement that the container have both an inlet and an outlet (a limitation not present in any of patented claims 15-18). Moreover, pending claim 22 requires that the solid primary amine actually be enclosed in the container. Claim 22 does not require that the amino acid source be enclosed within the container. It merely requires that the amino acid source be "configured to direct" an amino acid into the container. Implicitly, the amino acid itself needn't be enclosed within the container.

¹ See element (b), "neutralizes and removes."

It would have been obvious to have carried out the patented process using a container having a waste inlet and waste outlet in order to carry out the neutralization in a continuous flow process as is conventional in chemical processing technologies. Furthermore, it would have been obvious to have simply placed the amino acid in the most economical form it would have been supplied to the user from a chemical supplier, i.e., as a bulk solid powder (rather than an aqueous solution), and to have placed the solid amino acid in the flow through reactor, and then added the waste stream to the container.

Claims 22-24, 31 is rejected under 35 U.S.C. Sec. 103(a) as obvious over King, Wu, and JP 7204661 to Nagata.

King describes a device for purifying water. The device includes container having an inlet, and outlet, and purifying material pellets enclosed within the container. The pellets are, of course, solid, but they are not primary amines. Wu teaches that amino acid pellets were known. JP 7204661 describes using amino acids to neutralize glutaraldehyde. It would have been obvious to have placed the known amino acid tablets in

the King device to effect neutralization of glutaraldehyde in a continuous, flow through manner.

Claims 22-24, 31 are rejected under 35 USC § 102(e) as anticipated by Chen. USP 6399850 to Chen describes a device for removing aldehydes from a waste stream comprising a container (treatment tank) having an inlet and an outlet. The device also includes a source of solid primary amine enclosed within the container (see column 2 lines 59-60). The solid primary amine neutralizes and removes the aldehyde from the waste stream. Chen describes « amino acids » as including peptides/polypeptides formed by any number or any type of amino acids (col 4 line 16. The skilled artisan would have "at once envisaged" inter alia each of the 20 poly(AA) polypeptides, wherein "AA" is selected from the group of the 20 amino acids shown at Pine p.786-787. Not only would such polypeptides meet the limitation of a solid primary amine by virtue of the terminal amino group, but some, e.g., polylysine, would also comprise pendant amino groups, as discussed above. Note further that the amino acids described needn't be in free base form, but may be in any physical form. A salt, a common non-free base form, would have come to the

skilled artisan's mind (see Sigma product info sheet for poly(L-lysine) for example).

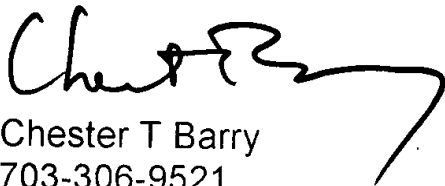
Claim 28 is objected to for misspelling of "polysaccharides."

Claims 22-25 are rejected under 35 U.S.C. Sec. 102(e) as anticipated by USP 6068980 to Decor. Decor describes chemical binding of a primary amine to a silica nanoparticle in a two-necked (i.e., two opening) flask. See Example I and Claims 28 and 30.

USP 5290440 to Pirkle is cited for its disclosure of prior art (vis-à-vis Pirkle '440) chromatographic supports comprising chiral selectors tethered to silica supports via amide linkages derived from primary amines. The skilled artisan would have understood that a chromatographic material would be placed in a container having an inlet and an outlet. It is unclear whether prior to amidization the primary amine was a portion of the chiral selector or first chemically bound to the silica support. If the latter is the case, then such disclosure would appear to anticipate at least claims 22, 23, and 25.

It is noted that two items cited by the examiner in the prosecution of USP 6399850 have been cited in IDS's filed in this case. There does not appear to have been a citation of USP 6399850 in this application. The application having docket no. ASP-009, cited at page 4, does not correspond to 09/321964 (now Chen '850).

Ref. I is cited for its discussion of CSTR and plug flow reactors.



Chester T Barry
703-306-9521
9/18/02

**CHESTER T. BARRY
PRIMARY EXAMINER**